

U.S. SMALL BUSINESS ADMINISTRATION

Warwick, RI Hearing

September 29, 2005



PROCEEDINGS

[START TAPE 1 SIDE A]

LEO: -there's this need for it to be made in a customized manner for [unintelligible]. We utilize the art history of pharmacy and have access to over 15,000 different chemicals and dispensing systems to create customized dosage forms. We do this both for people and we do this for animals as well, because animals as we well know, trying to give a cat a pill can be a challenging process in and of itself.

The problem I bring this morning is now a three year process that we have been attacking both as independent businesses and as a trade organization and we're also a member of the board of directors of the International Academy of Compounding Pharmacists, which represents the over 1,800 members in our organization nationwide that also are practitioners of the art of compounding pharmacy.

Our issue this morning, and I'm glad to see that someone from FDA is here, is a problem with the FDA that the Ombudsman's office and the Office of Advocacy has been involved with to attempt to create what we see are two very flawed policy guidelines called CPGs, Compliance Policy Guides. The problem that we as an industry have is that CPGs are not a part of the regulatory process of the federal agency. They are just the agencies view of the world. As such, they are not required to go through the official law making process and as such, none of the affected entities or any of the compounding pharmacists or pharmacies, have the ability to comment on these as they're being formulated by the agency. Rather, they are released by the agency as a take it or leave it view of the world and then are transmitted to the various state regulating boards or pharmacy. Every state in the country has a state board of pharmacy which are tasked to regulate the profession in their respective states.

Unfortunately, many states take these CPGs as gospel as to what they should be doing as a regulatory agency and there are several issues that we have raised about both the veterinary CPG, that has been problegated [phonetic] by the Center For Veterinary Medicine and the human CPG, that has been problegated by the Center For Drug Evaluation and CBE, I'm not sure what the acronym stands for, but it's CDER and CVM. I want to just explain the left hand and the right hand dichotomy that is just one aspect of this flawed compliance policy guide. If you were to bring in a prescription from your physician, instructing me as a practitioner to create a dosage form for a blood pressure condition using a drug called Atenolol, I am able to go to the shelf and take a vial of pure Atenolol powder off the shelf and create, upon the order of your physician, either a capsule, a tablet or a liquid to get you the exact dose of what you want, what you need

to treat the high blood pressure.

If you bring me the same prescription for the same drug for your cat, presently FDA policy says I can't use that chemical on the shelf. I have to go to the other shelf where I have tablets that are made by a manufacturer and use that as the base raw material to create the same dosage for your cat. It makes no sense and anyone that you explain this process too invariably nod their heads and say, "We don't understand either."

There's another aspect of the compliance policy guideline that says, pharmacies that compound these drugs will be treated as a manufacturer under several, if certain things are occurring and one of the requirements that is most onerous for us is that, if we use commercial-grade equipment, we are then deemed to be a manufacturer under the flawed compliance policy guidelines that currently exist under FDA. While I'm sure we have all seen the old fashioned balances that you put a weight on one side and you weigh out your powder on the other side and when the little lever is equal then you've got exactly what you're looking for. Well I think we can all recognize that technology in scales and equipment is much more accurate these days.

You go to the supermarket, they put the meat on the scale and what is it? It's a digital readout. We have balances that are made by nationally certified and approved companies that are accurate to 1mg, which is a very, very small amount of ingredient. The regulatory folks at FDA tell our members that that is commercial grade equipment and I hold that that is, yes, maybe commercial grade equipment, but it is a tool that is widely acceptable and widely utilized to do the best job that I can as a practitioner. Why guess about whether or not the balance is accurate when I can calibrate a digital scale and use that to precisely measure the exact amount of powder that we want to create a dosage from.

There's another device that we use that's called a V-blender. When you're taking small amounts of powder and you're suspending it in a dilly lin [phonetic] or a carrier, specifically lactose or methyl cellulose to create capsules, you want to ensure that that small amount of drug is dispersed evenly throughout that mixture so that when you make your capsules, your capsules will be exactly what you calculated them to be, or as close as humanly possible to that. The old style way of mixing it was to put the ingredients in a Ziploc bag and then walk around the pharmacy for 25-30 minutes with one person shaking it and the other person shaking it to disperse the drug.

There is a device that does that for you and it just mixes it in an automated fashion. Again that's commercial grade equipment and makes us, under their guidelines be a manufacturer. The debate about pharmacies being a manufacturer or pharmacies being pharmacies, is

that under federal law, the pharmacies would be regulated by the State Board of Pharmacy as a pharmacy and not, and be exempt from the FDA's manufacturing rules. FDA is attempting to drag us kicking and screaming into the manufacturing venue, that gives them the ability to walk in and conduct compliance orders and surveys and essentially stop us from taking care of patient's specific needs.

I was fortunate to have conversations over the last two years with both the prior Ombudsman and with Tom Sullivan, the Officer of Advocacy and his staff that continues to beat the drum for us. One of the promises that were [sic] made to us over the last several years by FDA was that these compliance policy guidelines would be reviewed and re-issued and as recently as yesterday there was a notice published by FDA that they were going to rewrite the veterinary CPG but they are still silent and still have not re-issued the human CPG. And the message that I want to bring back to FDA is, it would be a lot cleaner and a lot more positive and a lot better for small businesses if they brought the regulated entities into the process before they released us.

Bring us to the table, tell us what your needs are, tell us what the issues are that you want to try to solve and then how do we collaboratively as a regulated body and as the regulators, work together in the spirit of regulatory flexibility to change these flawed guidelines to free us from the shackles and fear of being shut down by the FDA, but at the same time allow us to provide quality patient healthcare. And I can give you examples upon examples, I could spend the morning giving you examples of how our members and how we as practitioners are solving patient-specific needs without endangering the manufacturing industry which has their own unique set of issues and concerns.

I'm hopeful that a dialogue that we've started over the last few years, I'll be happy to share with the representative from FDA this morning, but I think the message that I'm asking, not only the Ombudsman's office, but the Office of Advocacy to bring to FDA is, it's time for FDA to live up to their commitments and change these guidelines. And if they're going to do that, we're happy if they do that, I think the better solution is, change the process. Bring us into the mix now. Let us give you comments and feedback about how your suggested changes would affect us, so that we're not all wasting our mutually valuable time having to fight about it after it's done. Let's solve this in a collaborative fashion now and I want to thank the Office of Advocacy and the office of the Ombudsman for hearing me this morning, thank you.

MALE VOICE: Thank you Leo. Just for your information, CDER stands for the Center for Drug Evaluation and Research.

LEO: Thank you.

MALE VOICE: And I did receive a letter yesterday, that I found out about last night, that says that the second round of comments that you and your organization have filed are being reviewed by both the veterinary and the drug evaluation folks and that they will need additional time to coordinate a response. But they expect to have it for me by the end of November.

LEO: Good, well there'll be more coming.

MALE VOICE: Well that's great, you know? The more the merrier. The last time we did this, Leo's organization generated 100 comments. There are 25 right now on this second round which is, you know, the FDA said they were going to do this, they haven't done it and come on, get off the dime and we need results. So, anyway, thank you Leo. Yes sir?

MALE VOICE: Question for Leo and for you as well. It sounds to me like these compliance policy guidelines are really simply regulations in sheep's clothing and as a former regulator myself in the word [phonetic], that still strikes me as a clever, but perhaps barely legal way for a federal agency to be regulating its constituents. It really begs the question, whether the FDA really is circumventing standard regulatory procedure on a federal, it certainly would be on a state level in Massachusetts and it also would sound to be, in terms of guidelines. The FDA can very simply say, "I don't even have to listen to your suggestions--"

MALE VOICE: [Interposing] At least I'll give them credit for at least coming to the table and saying, "Okay, yes we will accept your comments and your suggestions, but we don't really have to."

MALE VOICE: There is a discussion in our group at the national level to request federal law change, banning FDA's ability to issue CPGs and forcing them to go to the federal regulatory process. That would give us a comment period under the federal administrative procedures act and then allow the Office of Advocacy to become involved at the, the birth [phonetic] stage, if you will, of the CPG.

Right now, there's no comment, there's no hearing, there's no input. It's just, "Here's our view of the world, have a nice day." And that's problematic for the industry.

MALE VOICE: The guideline has the force of regulation if its *de facto* a regulation.

MALE VOICE: Yep. I'm with you.

MALE VOICE: Norm [phonetic], did you get the comment from Jack Devlin [phonetic]?

NORM: Yes, I have a copy of it

MALE VOICE: Okay. David [phonetic], would you be willing

to read this comment?

DAVID: Yes. Would you like me to read it [unintelligible] or did you just?

[Crosstalk]

MALE VOICE: See if people can't attend these hearings, they have additional options because we try and be available as we can. One is, they can send us testimony and one of our three wonderful board members will read it into the records. We also have this little box up here for any talk, that if people said, "I just found out about this hearing, because I saw this guy on Channel 10 News this morning and I don't have time to get there, can I testify?" People can call in this way and we'll take their testimony. So we try to be as available as we can.

DAVID: This was submitted by John A. Devlin, United States Navy, a retired President [phonetic] and CLO of the Devlin Search Group Inc. which is quote, "A proud service disabled veteran owned firm." Good day sir. I will not be present at the Regulatory Fairness Hearing, Rhode Island [unintelligible] September 29th, due to scheduled travel and attendance of a semi-international meeting at which I am speaking.

However, based on a recent telephone call, I'd like to go on record with what I feel is a major problem that currently boards on Small Business Administration discrimination when it comes to service-disabled, veteran-owned, small business concerns and veteran-owned small businesses. SDBO [phonetic] and BO small business programs have been and continue to be supported by public law 106-50 [unintelligible] category of assigning 3% of the inventory goal [phonetic] to large business and inclusion of SDBO. A lot of [unintelligible] folks up here with me into the SF294-295 as a category, veteran's benefits acts of 2003, public law [unintelligible] 183 established a procurement program to include competitive set-asides and sole source awards at the government contracting level, but did not change the SF294 and SF295 [unintelligible].

On that same note, interim final rules issued on May 5th, 2004, with the final rule to be published concurrent with FAR change. In October 2004, the President of the United States issued an executive order, in effect mandating that federal agencies and departments exercise public law 108-183 [phonetic] to the fullest extent possible. To date, the SDBO and BO community has seen a doubling of contracts, according to SBA Office of Inspector General report to Congress [sic].

However, industry or government has failed to reach 1% in this category. Please note, no percentage of [unintelligible] these two groups, just the word and phrase "SDBO, SBC" doubled this past year. All of the categories of small business, [unintelligible] women

[unintelligible] were [unintelligible] in attained percentages, generally made the goals or came close. In an attempt to identify why SDBO BO business is or have [sic] problems and issues, one or of two SBA programs jumps out [sic]. In 1998, an SBA program was put in place and funded every year since [unintelligible] assistance program, SBA, SOP 60035.

What is the Subcontracting Assistance Program? In the United States, the Government's large business fund practice purchases millions of dollars in products and services every year for companies in the private sector. The Subcontracting Assistance Program is the Small Business Administration's vehicle to increase the percentage of subcontract awards to small businesses and to make sure that small businesses throughout the country receive a fair and equitable opportunity to compete.

What is the Subcontracting Assistance Program's mission? The primary mission of the Program is to promote maximum possible use of small businesses by the nation's large contractors. The secondary objective of the program is to make sure that the requirements of all applicable laws are satisfied up above any [phonetic] 5-507 past the 1978 legislation [phonetic] 8D of the Small Business Act, [unintelligible]. 5-507 was a landmark legislation for the foundation of the Subcontracting Assistance Program. This law requires that other than small businesses are [phonetic] awarded federal contracts, to submit it to subcontracting plans of [phonetic] the contracting agency if the contract exceeds \$500,000 or \$1 million for construction of a public facility and offers further subcontracting opportunities.

The Subcontracting Plan establishes separate goals for subcontracting through small, small disadvantaged and women-owned small business. The Subcontracting Plan also contains several other elements required by law. Once the government has approved it, the plan becomes a material part of the contract. Federal Acquisition Regulations, FAR, sets forth the requirements for subcontracting plans and compartmenting [phonetic] teams, sub part 19.7 and clause 52.219.9. Please note, SDBO, SBC or BO is not mentioned.

What is a commercial market representative, or CMR? The Commercial Market Representative is a specialist assigned to the subcontracting assistance program who facilitates the process of matching large business contractors with small, small disadvantaged and women-owned small businesses. CMR's identified, developed and marketed small businesses to the large contractors and assists the small businesses in obtaining subcontracts. CMR also performs compliance reviews on large contractor's subcontracting programs to ensure compliance with all applicable laws and SDBO or BO have no notice [phonetic] to these people.

What is the CMR's portfolio? The portfolio is a list of large business contractors with one or more federal contracts over \$500,000, normally for construction, and take [phonetic] the subtracting plan, assign it to a CMR within his or her respective geographic area of responsibility. CMR conducts specific compliance reviews and needs assessments of the companies that used their [phonetic] portfolio.

What is the legislative authority for the Subcontracting, excuse me, Program? The basic legislative authority for the Subcontracting Assistance Program is section 8D of the Small Business Act, [unintelligible] by public law 95-507. Section 8D is now codified [phonetic] in 15 USC [phonetic] 637D. This legislation designated SBA as the principal government agency responsible for enforcing provisions of the law pertaining to subcontracting plans.

The Federal Acquisitions Streamline acts, line [phonetic], public law 103 and 355, sections 8D and 15G of the Small Business Act, all references to small, small disadvantaged and business programs and subcontracting plans were changed to small, small disadvantaged and women-owned small business programs and subcontracting plans. FASA also established a five goal [phonetic], contracts to women who own small businesses and brought [phonetic] the prime contractor and second contractor [unintelligible], effective date January 26th, 1998.

Note, there has not been an update to this SOP [unintelligible] issuance, PO 106 50, PO 108 183 and [unintelligible]. [Unintelligible] SBA headquarters and the area directors for government contracting for this program. SBA headquarters, the Subcontracting Assistance Program is administrated by the Office of Industrial Assistance, which is responsible for developing national program policy. This office reports to the associate administrator for government contracting, whose responsibilities include gathering statistical data from the field [phonetic] on a periodic basis.

[Background noise]

DAVID: -to ensure compliance [unintelligible], distributing information to the [unintelligible], providing technical assistance as a service to the field [phonetic], interpreting new legislation to establish a policy [unintelligible] program-

[Background noise]

DAVID: -recommending new legislation for the associate deputy administrator for government contracting in minority enterprise development, handling problems in the field-

[Background noise]

DAVID: -developing training programs for CMRs on a national level, [unintelligible] award for distinction, award of distinction, like

the Eisenhower Award for Excellent, Contractor of the Year and [unintelligible] new programs. This includes obtaining clearance from the Office of the Sector General and the Office of Civil Rights Compliance are all [unintelligible] to be [unintelligible] these awards.

Garry [unintelligible], the director for government contracting is responsible for administering the Subcontracting Assistance Program in the field. He's accomplished this mission by delegating specific program requirements to the commercial market representatives for CMR and their staffs. He apies [phonetic] or delegate's responsibilities include supervising the staff of CMRs, providing guidance and direction to CMRs as necessary, [unintelligible] and coordinating SBA's large contractor incentives at the area level, who in the award of distinction [unintelligible] the Eisenhower Award, managing and coordinating subcontractor of the year and prime contractor of the year award programs at the hearing level.

Apparently there are 50 PCRs in 28 states, covering 255 volume in tips [phonetic] -

[Background noise]

DAVID: -on site at 1999 of the top [unintelligible] activities, 25 of the 50 performed other than PCR functions. [Unintelligible] of competencies, size determinations, subcontractor compliance reviews, [coughing] focuses is counseling. At present, SBA has nine CMRs that grow [phonetic] 70%, award their time to subcontracting. Even in 1995, SBA only had 18 [unintelligible] CMRs.

So what does this mean to SDBO, SBC and BO small businesses? On-site compliance, small business point [phonetic] reviews had been supplemented with desk review to conserve the travel votes [phonetic]. In 2003, a memorandum of understanding was executed with the Defense Contract Management Agency and currently routes [phonetic] are being brought to DOT. Electronic subcontractor recording systems is being developed by SBA to replace the [unintelligible] coordinates of 295 for all federal contractors. Its goal, calculated percentages automatically, provides an entrail [phonetic] showing who entered the data or revised it.

It does nothing to help the SDBO, SBC or BO small business the SBP goal, which is really not a goal, but a material part of the contract with provisions for which to sue material breach of contract could be filed against the firm [sic].

Finally there's the appearance that almost every prime [phonetic] is making their small business calls. In fact, SBA just announced last week attainment of 23%. The real world is still out concerning what is small business about, is that being coveted for the 23% [sic]. On reviews the SF294 and SF293, which I have in hand [coughing] each

and every one, with six identified, disadvantaged diversify categories, do [phonetic] generally make the calls. The others woefully [unintelligible] too, again, how much investment was made by the recording prime contractor in those past through [phonetic] businesses they hold a vested interest in.

It's understood that some major crimes recoming [phonetic] value added investors and use SBCs for the profitability and recording in the SF294 and SF295 goals in support of SPB. In conclusion, SBA must hold themselves at fault, and that's where this focus [phonetic] is champion image. SBA administrator, Hector V. Barreto stated that it's important the SBA be a small business partner, to be an advocate for small business and to be the agency that small business holds [phonetic] on to respond to its needs.

From my perspective, I just want the SBA to follow and execute the current policy and program initiatives currently in place and other books [phonetic] regarding size standards, aid [unintelligible] large business versus small business contractor awards, [unintelligible] programs and [unintelligible] programs. Making the Subcontracting Assistance Program work, with SDBO, BO and other categories would certainly add fuel to that and which drives the United States' economy, small business [unintelligible] president speaks about.

Thank you for the opportunity to enter into the record this plea for conformance [phonetic] and equal seating at the prime contractor's table. I do hope your task force understands that the BOS, DBO, SBC awards [phonetic] were [unintelligible] for you and now we really don't want to enjoy a place at the end of the line, just provide fair and equal treatment and make the SBP work for everyone. [Unintelligible] information here, if you have any questions please free to contact me at 558 725 8000, or by email [unintelligible]@usa.net

[Unintelligible] respectively by [unintelligible] double United States Navy retired, president and CEO of the Devlin Search Group Inc. [unintelligible] crowd service disabled veterans-

[Background noise]

MALE VOICE: Thank you, David.

FEMALE VOICE: A synopsis please?

[Laughter]

MALE VOICE: Who would like this document and where would you like me to put it?

[Laughter]

MALE VOICE: Thank you.

FEMALE VOICE: Wow.

MALE VOICE: First of all this testimony points out that the SBA is not exempt from consideration by any small business that thinks they've got a problem with a federal agency. This guy knows more about the SBA than I do. He spends more time, apparently, researching what the SBA is doing than he does selling. You know? We've got this problem sometimes with small businesses in particular that, once they get established as a woman-owned business or an ayday [phonetic] business and they're eligible for set-asides, they sit there and wait for their contracts.

They say, "I did the paperwork. I'm now qualified. Come to me government, write me checks, give me business." But it doesn't work that way. You have to go out and sell, just like anything else. The SBA has exceeded its collective small business goal with government contracting. We can always do more. There's obviously an emphasis right now the hurricane affected areas. In fact I've got to go back and get into that next because the administrator wants to make sure that we're able to do things for the small businesses who are impacted by exactly this problem.

The prime contractors come in because they're relied upon by the agencies, the agencies know them, they know their capabilities, they've got to get a job done. The president said, "I want this done." And as a result they are out there and they're getting the contracts and they're taking the action, bringing in the people. In fact, I've got a board member who's working for one of the primes, but he's not working on the hurricane things, he's working on Iraq because this particular, large company has diverted all their resources to the coast area to try and rebuild and do it now.

So they brought him in as a consultant to over see at a distance what's going on with their personnel in Iraq. But I'm astounded at all the things that he has in here and all the details. He's done his research, I think. But the result he will get, as I said, you get an answer out of my office and we will take this and we will see what we can find out from the parts of the organization you referred to. You know, we've got the veteran's affair guy, we've got the government contracting and business development person, we've got, you know, various parts of the agency that he suggests are not doing their job.

Well I will take this to each of those, parts of the agency and ask them for an answer, just like I ask labor or the FCC or USDA because that's what small business people need. Again, David you did a great job reading this thing. I don't know what all he's got in here [sic], you know he's got things about the Far East, got things about all kinds of stuff, but anyway, we'll take some action.

Do we have somebody else who's prepared to testify this

morning? Please.

MR. JOHN WILLIAMS: Sorry I'm late, one-man show gets to turn out that way. Specific complaints, I'm not going to read, don't worry.

[Laughter]

Mr. JOHN WILLIAMS: I'm John Williams [phonetic], I own Water Cool Marina [phonetic], it's a little [unintelligible]. I bought it in '94. It's been in existence since the thirties. My specific complaint relates to [unintelligible] regulation and how they're implemented, carried out between national fisheries, EPA, army corps, DEM. I have tried for 11 years to obtain a dredging permit to fully utilize my facility. I have not as much as received a letter indicating the deficiencies that I need to address, specifically from National Marine Fisheries in Milford, Connecticut.

I'd give you the gentlemen's name but I don't think it's fair. DEM and army corps all seem complicit from the perspective that I cannot come up, I cannot design, engineer a document that allows me to use my facility. I spent six months on a technical subcommittee working with a number of environmental groups including regulators and another, over two years, almost two and half years, coming up with this, this beast that was called a special area management plan for Greenwich Bay.

I have some charts if you have an interest in geographically getting an idea. This is Greenwich Bay. It is a small subset of Mariganta [phonetic] Bay. This gives you an idea of the scale that we are dealing with.

[Background noise]

MR. JOHN WILLIAMS: Yes, as a matter of fact, my facility is right here and we are currently, geographically located just about right here, which is not very far from the cove.

Okay, at the conclusion of this report, which was nationally recognized as being one of the most advanced documents that a community group had worked on, it had brought into consideration not only environmental impacts, but economic impacts. And the number and diversity of people who use the bay, including marinas who, much like myself, provide public access to the bay for people. There is a discrepancy or a discussion rather between whether or not public access means free and marinas are considered a private entity.

However I view them in a similar light as a parking garage at an airport. It is therefore everyone's use as long as they remunerate the investor so that they can continue business. In all this time, as I said before, I have not received a single document, letter indicating how I can successfully execute what should be offered, what should be

available as a portion of my business. Street water run off has been a big problem no matter where you go. It fills my facility in.

I have another thing if you can take a moment to look at it. This is also an aerial photograph of the cove and my facility is just right here, right in this area. They give you-

[Background noise]

MR. JOHN WILLIAMS: This is a photograph going back to a previous hurricane. This facility was about the only facility in existence. You'll note that a number of other facilities have developed since then, but this place has been there a very time.

FEMALE VOICE: Do you still have the same number of moorings that you did originally?

MR. JOHN WILLIAMS: No, it has expanded over the years to some extent, but it's done that for several reasons. The federal channel was defined. At that point in time there was no federal channel. Once the federal channel was defined then we could determine what repairing the rates were. So there have been previous expansions but this photograph goes back seven or eight years and while I have reorganized the docks, the overall dimension in terms of the number of slips hasn't changed very much. And we've never been able to use all of the slips, to put them in the water. We've never been able to use all of them that I carry a license for.

Here, a license for 135, I currently have 100 because I can't dredge to get sufficient water depth for the ones that we do have a license for.

MALE VOICE: Do any of the other marinas that I see on this map-

[Crosstalk]

MALE VOICE: -have that problem. What?

MR. JOHN WILLIAMS: About two years ago the army corps, national marine fisheries, EPA decided they want to rebuild Sachuest Point Marsh area, down in Newport. A facility in my cove, 500 feet from mine worked out an arrangement where they would dredge, put material on the barge, take the barge to Sachuest Point and have it dropped off to rebuild this marsh. It was basically a brown field that they were rebuilding. They did this, our dredge window is considered two months so that we don't interfere with the reproductive attributes of the fish.

That project was executed over three months out of season, suspend whatever rules they needed to so they could do what they needed to do. It just didn't matter. If someone else was going to pick up the tab so they could have their pet project, that was okay with

them. And we have a problem in Rhode Island, it's called ice. During the months that we're normally allowed to dredge, we're iced in. It's not at all unusual. It strikes me that there's a great deal more philosophizing that goes on around wetlands regulation than there is science.

I've worked on science, I came from science and I don't believe they're honestly or fairly allowing property owners to use their facilities, which we're [unintelligible] specifically. Before we build new, more marinas, we wanted everyone to have the capacity to build out to what they currently have. That only makes sense and here we are, 11 of this. 11 years, I haven't received a single document indicating, "John, for you to become successful at dredging your facility, you need to do these things." I got literally, at least 1,000 man hours in this project between engineering time, my wetlands experts time. I've received permits ranging from [unintelligible], building docks to replacing gas tanks. I have never found the need to use an attorney in order to reach a reasonable conclusion with the regulators, including underground storage tank units.

We can always find a way to get things done if they were reasoned and we could find a way to get an accomplishment. And in this regard, no matter what I've done, I've not been able to find that answer. So this time around I'm going to get an aggressive environmental attorney to push back. It's truly unfortunate because I do have a sincere effort in maintaining and improving the environment.

All this summer I've worked with a volunteer group. I do probably six to eight hours every Saturday morning to afternoon, taking water quality measurements around Greenwich Bay. I know about this health [phonetic] oxygen around Greenwich Bay than most of the local experts and I'm a volunteer. I use my own boat, use my own gas, spend my own time. So when someone comes from Connecticut and they want to philosophize about their desire and don't understand, I've seen things that that group has written that were absolutely, technically wrong. I'm not saying a little bit wrong, I'm saying these guys were OLT, Out To Lunch.

There is, the cove I am in, Warwick Cove, has the greatest number of boats in the bay, the density of boats. That picture might give you an idea and there are more than what that picture indicates. It is the cleanest and highest dissolved-

[Background noise]

MR. JOHN WILLIAMS: -than any of the four coves around Greenwich Bay. An adjacent cove, just to the west of ours is called Brushneck Cove. It has almost no boats at all, maybe a dozen or so. It has the worst water quality. So for the individuals who have prevented any kind of development, any kind of water front, they say basically

it's a philosophical position that says boats are bad. It's truly unfortunate that facts don't even come close to what they're imagining.

Boats actually can improve and have improved dissolved oxygen in these coves. Their own philosophy doesn't stand up to reality and it's as if they're dealing with suspended disbelief because it isn't what I want, it isn't what I think. I did not bring, or did I? I did not bring, I have a toxicological report done for my facility, indicating, specifying all the minerals, chemicals that are tested. And you get this chart, a fairly, \$8,000 chart and my material passes for what should be called playground sand. It is that good but the [unintelligible] doesn't want to deal with that. It's all, "Well we know it's dirty because we think it's dirty."

And that's what they're doing, I wish they'd stop. I'd like to get a letter from them. If you could help me get a letter from National Fisheries indicating what is deficient. I've had phone calls. I've redesigned this project, major revision three times towards the marsh issue. I've never been offered a letter that said, "If you do this and this, we will award you a permit." It never happened.

FEMALE VOICE: Do you get replies?

MR. JOHN WILLIAMS: I'm going through not only mine, but other people's applications. This isn't the entirety, these are just a few documents I'm going to give my attorney, okay? Other people have gotten responses, but it's very, fairly rare. Everything is done in myriad terms. It's all about innuendo. It's all about, "You need to be an expert." You know what? I went to MIT, yeah I can [unintelligible]. So when they say, "We started out with a design that hardly touched the marsh at all. Then we went to Rip-Wrap, submitted all the documents for Rip-Wrap to sign. No. Submitted documents initially for bulk head design. No. Rip-Wrap? No.

We [unintelligible] a mezzanine. We decided that [unintelligible] have a metal mezzanine to maintain the marsh level, but would have six quart of water in the front and that would basically build a shelf, a private shelf for this one marsh area. No.

MALE VOICE: Who said no?

MR. JOHN WILLIAMS: What do you want me to do? National Fisheries.

FEMALE VOICE: So you do get a response-
[Crosstalk]

FEMALE VOICE: -you don't get any in writing?

MR. JOHN WILLIAMS: No, I haven't even-
[Background noise]

MR. JOHN WILLIAMS: -like I said. We've manage to replace all my gas tanks in '99 without getting-

[Crosstalk]

MR. JOHN WILLIAMS: -there wasn't regulations, they say you're supposed to do restitutions. We investigated the adjacent cove so I could move my marsh and put it to some place where it was beneficial, useful and regain a utilitarian function that it didn't originally have. Then they come back and say, "Oh no, you can't use any property that's owned by the federal government. You cannot use any property that's owned by the state or the city government, it has to be private." And then they said I couldn't use the adjacent cove, we're talking about an area a half a mile away from here, couldn't use the adjacent cove, it had to be in my cove. It not only had to be in my cove, but it had to be private property. So here's where that result, this took nine months, so the result was, I approach a friend of mine who's got approximately 600 [unintelligible].

And I said, "Jim, if I do this, if I re-grade, re-build and I do a two to one make up, which is the requirement. For every 1,000 square feet I put in my 1,000 plus provide 1,000." And so if I put that right in front of his marsh, I wanted to be assured from DDM or NIFS that I would not be removing or sealing off his reparian [phonetic] right the future. This is one way they gain control of private property, they basically seal it off.

I was never able to get that letter. I was never able to assure my friend that his reparian rights would still exist if I put a marsh in front of his marsh. And I later found out that in fact that's what they were doing. Once you seal, once you put the strip along the front, they consider that, the entirety of that a restoration project and you could not put a private dock across that front. Do you see what I'm getting at?

So basically I'm removing his reparian right as a citizen because he was trying to help me do the right thing. None of this shows up in documentation.

MALE VOICE: How many other people or businesses are in your situation?

MR. JOHN WILLIAMS: I think I'm the worst situation, but then again it's how I feel about it. I know that, we haven't had dredging in [unintelligible] for 30 years. Our own [phonetic] regulation has had significant impact in persuading anyone from doing that. I wish there was a way that we could find a reasonable alternative, for us to get our job done and protect the environment. There is a thought that marinas are specifically a dirty place and what I'm constantly trying to convey people of [sic] is that my best interest is in clean water.

Those are my customers. I want the bay clean. I have no interest in destroying the goose that lays the golden egg. Jeez, it doesn't even make common sense. It strikes me that it's almost like an easy way out. If they just say, "Oh it's private enterprise, they shouldn't be involved in this anyway." But if we weren't there to provide public access, I'll tell you, there aren't too many neighbors I know would let you cut through the yard so you can put your boat in.

So I mean that's what marinas are there for and no offence, but the federal government hasn't done a very good job of providing public ramps or parking. Not the allocation of blame, I'm just saying that portion of access to the bay has not maintained the pressure or the interest in using the bay as a resources, as a recreational resource.

MALE VOICE: Is that not a state activity?

MR. JOHN WILLIAMS: State in effect. I mean you guys come up [unintelligible] an awful lot of money.

[Crosstalk]

MALE VOICE: But we don't tell the states how to spend it.

MR. JOHN WILLIAMS: You collect 18 cents a gallon on every gallon of gas that's sold in [unintelligible] Bay.

FEMALE VOICE: Is that the state or the federal one?

MR. JOHN WILLIAMS: Federal.

[Crosstalk]

MR. JOHN WILLIAMS: Maybe occasionally we get, I know Senator Chaffee, when he was mayor, also worked on a public ramp which is right in my district. 500 feet away from me is a beautiful, beautiful ramp and it's clogged every weekend. It's absolutely fully utilized all the time. If we had five more of those in this city you maybe all would break even [sic]. But there really is a lot of pressure to get out there, still a lot of people who have an interest and dredging is one aspect of this.

You know, the city doesn't seem to have a great deal of interest in preventing surface water run off from filling my place in. But the feds seem to have a disproportionate interest in making sure that much as [unintelligible] can't take it off. They're in love with this marsh issue. I'll give them all the marsh they want. You know I've only got 500-600 linear [phonetic] feet to use. Can I put it in the mile, the adjacent cove, see if I can show it.

This cove goes back a mile. There's nothing in it and there are surface water entrances into this cove that have a blow out, what we call a blowout where street run off converges. It rushes so hard that it literally erodes a whole right in the marsh. At that point in time, the filtration benefits of the marsh are obviated because the water always

goes to the low point. You move my couple thousand square foot of marsh and let me rebuild that and put in a plenum so that we distribute the water and we don't get high speed during hard rain events. It's pretty simple.

We should have done that and put the marsh to good use. Instead they say, "No, leave it right where it is." It's got a lot more to do with philosophy I think than rules. So I know I've trip [phonetic] a lot your guy's time, thank you very much.

MALE VOICE: You're not done.

[Crosstalk]

MALE VOICE: You mentioned three federal agencies. The army core engineers, the EPA and the National Marine Fisheries.

MR. JOHN WILLIAMS: Yes.

MALE VOICE: Have you actually applied for specific permits from-

MR. JOHN WILLIAMS: [Interposing] The application process, defined in Rhode Island, the original application goes to CRMC, Costal Resources Management Council. From that point in time it is distributed to DEM. DEM works with National Fisheries, CRMC works with the army core of engineers, okay? The EPS works with DEM. So you get, there's always a single receiver.

What I have done in the past, is I provide the six [unintelligible] copies that they specifically, we're talking about, an application package is like this, okay? And we've done a number of them.

The application goes into CRMC. They're supposed to take care of the internal distribution. What I have done in the past was mailed separate copies to the few individuals that are always doing the same thing, because after a while you get to know who they are. So I sent another set to army corps, like Elliot up at army core, okay? And DEM and go that route so that I know they, everyone has more than enough paperwork to do the review. We're not struggling with one last piece of paper and trying to get three people [unintelligible] paper.

MALE VOICE: You've never gotten a formal, written response to that application you sent to CRMC?

MR. JOHN WILLIAMS: Right, either rejection, certainly not acceptance, no rejection and the worst of that is, I would like a clear, unambiguous path to success so I can use my own private property in its best capacity. And as time goes by, every year that goes by, I keep losing water because it gets shower and shower and shower.

I asked an individual, I said, "Would you rather just see me out of business?" and he basically said, "Yes."

FEMALE VOICE: Can I ask a question?

MR. JOHN WILLIAMS: Sure.

FEMALE VOICE: You said you have these additional piers that you can't put in the water because you don't have enough depth.

MR. JOHN WILLIAMS: My permit allows for 135.

FEMALE VOICE: So you have a permit and I presume when you got that permit it was on the basis that you have the space to put these in the cove and that they could be utilized. So when did you get that permit and from who?

MR. JOHN WILLIAMS: Oh gee that permit goes back. That was, I purchased the marina in '94. That permit had been applied for, but not received, by the previous owners. When I purchased the facility, I also purchased the rights to the name, the telephone number, on-going permitting activity with CRMC. So we continued that.

FEMALE VOICE: But you did get permission for that?

MR. JOHN WILLIAMS: We did, but since then, without a permit to dredge and get to that number, it keeps getting more and more shallow. It's going to be a great place for canoes in 20 years.

[Crosstalk]

MALE VOICE: Correct me if I'm wrong, isn't it the army corps that's responsible for dredging?

MR. JOHN WILLIAMS: Army corps is an inclusive agency whose permission is required to obtain, when you go for a dredging permit, the only people that I'm aware of that don't get a shot at it is the National League of Women Voters. Other than that I believe everyone else, you know.

MALE VOICE: Hell, we can fix that. Write that down.

[Crosstalk]

FEMALE VOICE: That's true in every other state too.

MR. JOHN WILLIAMS: But I think that's fair. Local environmental groups, the neighborhood association, we've actually received permission, a tough one from the city council to do uplands disposal. That was a tough one to get. That one we've got, we just can't figure out how we're going to actually get this [unintelligible]. But when it suits them, it just in a heartbeat, well out of season, way out of season. We have a coham [phonetic] transplant program in the state, which I know is executed in other states. One of the reasons that are often mentioned is that, so that there's settle time for any silt in the water [unintelligible] and it doesn't, over the flounder and all this other stuff, okay? Two weeks after, this is the facility that was dredged, right here. Two weeks after this was done, you can't see that dock right

there, but that's a camp, it's a navigational camp. They were digging a transplant program through this entire area, right in front of my place and I know a lot of the guys that are co-harbors [phonetic]. The stuff came out beautiful, no sand, no muck, no nothing.

So when I hear what they're trying to protect, it isn't validated by the exact science that I've seen. Got a question, what's really underneath? And I think what's underneath is they have a philosophical position that, and they support that at all costs.

FEMALE VOICE: When you make your applications and you send it to the proper entity that then distributes it to the rest, doesn't it have something on it that they must either accept or reject you by a certain number of days?

MR. JOHN WILLIAMS: That is the point and reason-
[Crosstalk]

MR. JOHN WILLIAMS: -aggressive, environmental attorney.

FEMALE VOICE: Right.

MR. JOHN WILLIAMS: I may still lose but damn it I want them to at least work for it. 11 years.

FEMALE VOICE: Some times in the state of Maine, you do have to do that and they are required within a certain-
[Crosstalk]

FEMALE VOICE: -and some people I know claim that they reject it rather than accept it. It's a way of delaying it, but they have to. I'm just astounded that you've never got a piece of paper, that's just amazing.

MR. JOHN WILLIAMS: And you know how it goes, every single little bit, you know you need to slide over and reorientate this a little bit and I'll have my engineers spend another 50 hours on redoing, coming up with new [unintelligible]. The shading of the gray where the bulkhead is supposed to be is a little off, can you do that so it's easier to reproduce? And I'm going, "Guys, tie it up. Really, really tie it up."

This time around, I'm going to spend my money on an attorney, not an engineer-

[Crosstalk]

MR. JOHN WILLIAMS: -doing themselves any good, from an environmental standpoint. Like I said, we've been measuring water quality in this area all summer because of difficulties and it does not validate the assertions that they're making. If I could prove to data sep [phonetic], it's not there.

FEMALE VOICE: In your submissions that you have made to

this Ombudsman, the agency, have you included these applications that you've made over the years?

MR. JOHN WILLIAMS: No, no-

FEMALE VOICE: [Interposing] I would suggest that-

MR. JOHN WILLIAMS: [Interposing] This is truly an act of desperation.

[Crosstalk]

FEMALE VOICE: They do need that specific information, when you made these applications and-

[Crosstalk]

MR. JOHN WILLIAMS: -matter of public record on CRMC.

MALE VOICE: Well you can go ahead and hire an attorney and spend your money if you want to do that. You can also give me a shot at it by filing a comment with documentation of what these various agencies have done. We'll split it out based on the responses of the various agencies and we'll ask each of them for an answer.

MR. JOHN WILLIAMS: Okay, do you have a card? Well I have your address from the-

[Crosstalk]

FEMALE VOICE: It's right in this one.

MALE VOICE: It sounds to me that your problem may not so much be the bad guys at the federal agency level but the state level-

[Crosstalk]

MR. JOHN WILLIAMS: The impression that I'm receiving is that it's a federal agency that wants to impose their will. I have seen things written by the federal agent that were just-

[Crosstalk]

MR. JOHN WILLIAMS: No, someone else's. I've never received this [unintelligible], someone else. And they want, consider [unintelligible] and I work, I used to be the mariner chair for the Rhode Island Marine Trades Association. And we worked hard at having no discharge for the entirety of the bay. We were one of the first ones to do that.

This is considered fairly clear water, but when you get into these little coves and little pockets, I end up with this organic material that builds up. So when an individual makes the assertion that this area is considered type one water, it's classified a certain way, well not when you get into the pockets. And what they're doing is, they're misconstruing this and they're imposing this standard on this pocket to scare you not to do something.

MALE VOICE: I've never heard of that before.

MR. JOHN WILLIAMS: I can imagine you haven't.

MALE VOICE: I can't speak for past directors, but the new director at DEM-

MR. JOHN WILLIAMS: [Interposing] Mike Sullivan.

MALE VOICE: -Sullivan, he's the scientist. So I think you have at least a friendly ear about the science of what your proposal is, for discussions with DEM and CRM [unintelligible].

MR. JOHN WILLIAMS: I've gone through four DEM directors, okay? So I like the guy, then again I get pretty well with [unintelligible] too. So anyway you guys showed up in town, so I said, "Hey I'll complain to them, maybe they can help me."

MALE VOICE: Well we can't so, well we can at least get you an answer. I mean why do you have this small business on ignore basically-

MR. JOHN WILLIAMS: [Interposing] -expect, believe it or not, we actually have those. I've a wetlands expert and I'll see if she and I can put together leafest [phonetic] number of documents to validate our previous applications. How does that do? At least then you know what we asked for, okay? And I've gone back-

FEMALE VOICE: [Interposing] I think that they need to know that you made complete applications and they need to have the dates on which those applications were-

MR. JOHN WILLIAMS: [Interposing] Here's another hidden little thing that goes on-

FEMALE VOICE: [Interposing] That's what my attorney's always taught me to do.

MR. JOHN WILLIAMS: If I'm making an application, for instance if I make an application and '97 was my first maiden may [phonetic], first major, critical application. "Oh we don't like it." So they make you apply again in '89 or '90. Well this application should have been awarded an extension of time so that this one reflected the rules set that existed in '97.

Every time we go this, they say, "Oh no, none of those elements ever counted. We're going to make you live up to the 2000." I've done this in 2002, 2003. Now we have to live up to the 2003 rule set.

FEMALE VOICE: That's because they don't acknowledge your application-

MR. JOHN WILLIAMS: [Interposing] Well I want my attorney to fix that. I want to go back and I want him to go back and fight for the name, sent me an application, sure I'm getting it [phonetic]? And

it's a game, it's a game.

MALE VOICE: Well I can only take your-

MR. JOHN WILLIAMS: [Interposing] The people are losing because they no longer have, I have about the cheapest marina in the state which is why I dress so well.

MALE VOICE: I can't take care the state of the stuff [sic] but.

MR. JOHN WILLIAMS: I can wear those all day.

MALE VOICE: Federal agency actions I can handle and I'll get you an answer.

MR. JOHN WILLIAMS: Very good.

[Crosstalk]

MALE VOICE: Thank you for coming.

MR. JOHN WILLIAMS: Thank you very much for your time.

MALE VOICE: Good luck. Just get that into me as soon as possible so that, okay?

MR. JOHN WILLIAMS: I will.

MALE VOICE: Is there anybody else who would like to step forward at this time? If not, yes sir?

MALE VOICE: Your appearance on Channel 10 apparently has had an impact. You received a call at the district office from yet another disabled veteran who has some issues with taxation and social security. So he's going to submit. He wants to put his thoughts in writing. He's going to email it and he'd like it to be part of this procedure today if that's possible?

MALE VOICE: We'll make it happen.

MALE VOICE: Okay.

MALE VOICE: Anyway, I want to thank you all for coming. I want to thank my board members for taking the time out of their busy schedules, the federal agency folks who came here so they'd get good grades. Thank you, the people who came to listen and I hope that anybody who's here, if they hear of a problem that a small business is having, that you'll refer them to us and we'll take it and run with it. Like I said, I don't promise the answers people want, but I promise an answer and we'll get it done. So anyway, thank you very much.

[Crosstalk]

[END TRANSCRIPT]